

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: **Garvey et al**

Serial No.: **Not Yet Assigned**

Filing Date: **December 21, 2001**

Title: **Nitrosated and Nitrosylated Alpha-Adrenergic Receptor  
Antagonist Compounds, Compositions and Their Uses**

Docket Number: **102258.346 US2**

**ATTN: BOX PATENT APPLICATION**

Assistant Commissioner for Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Prior to consideration of the above application on the merits, please enter the following amendment without prejudice.

**IN THE CLAIMS:**

Attached hereto as Appendix 1 is a copy of the pending claims. Attached hereto as Appendix 2 is a copy of the amendments made to the claims.

**I. Remarks**

After entry of the preliminary amendment, claims 35-37 are pending in the application.

Claims 1-34 have been canceled, without prejudice.

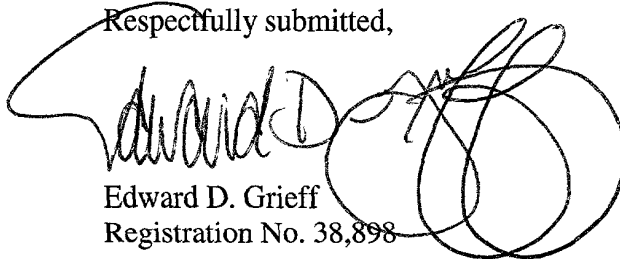
Added claim 35 is identical to claim 1 of U.S. Patent No. 6,165,975, issued on December 26, 2000. Pursuant to 37 CFR § 1.606 and § 1.607, Applicants request that an interference be declared with U.S. Patent No. 6,165,975.

Added claim 36 is identical to claim 1 of U.S. Patent No. 6,306,841, issued on October 23, 2001. Pursuant to 37 CFR § 1.606 and § 1.607, Applicants request that an interference be declared with U.S. Patent No. 6,306,841.

Added claim 37 is identical to claim 1 of U.S. Patent No. 6,013,002, issued on February 29, 2000. Pursuant to 37 CFR § 1.606 and § 1.607, Applicants request that an interference be declared with U.S. Patent No. 6,013,002.

No issues of new matter should arise and entry of the amendment is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Edward D. Grieff', is written over a large, circular, stylized scribble or stamp.

Edward D. Grieff  
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Date: December 21, 2001

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**Appendix 1 – Pending Claims**

35. (New) A method of treatment, in an organism, of a vascular condition, comprising administration of at least one agent at a level which enhances NO and which does not appreciably alter normal systemic vascular tone in said organism.

36. (New) A method for treating sexual dysfunction in a female individual, comprising administering to the vagina, vulvar area and/or urethra of the individual a pharmaceutical formulation that comprises an effective amount of a nitrovasodilator selected from the group consisting of sodium nitroprusside, diazenium diolates, molsidomine, linsidomine chlorohydrate, S-nitrosothiols, organic nitrates, pharmacologically acceptable salts, esters, analogs, derivatives, prodrugs and inclusion complexes of any of the foregoing, and combinations thereof.

37. (New) A method of enhancing sexuality in a female having a clitoris comprising the step of topically administering to a surface of the clitoris a composition whose primary agent is a vasodilator and whose secondary agent is a carrier in which the vasodilator is dispersed to deliver it directly to said surface so that it is retained and absorbed thereby, said composition being in a formulation and in a dosage which is substantially free of toxicity and therefore does not give rise to an adverse reaction.

**Appendix 2 – Amendments to Claims**

Cancel claims 1-34, without prejudice.

35. (New) A method of treatment, in an organism, of a vascular condition, comprising administration of at least one agent at a level which enhances NO and which does not appreciably alter normal systemic vascular tone in said organism.

36. (New) A method for treating sexual dysfunction in a female individual, comprising administering to the vagina, vulvar area and/or urethra of the individual a pharmaceutical formulation that comprises an effective amount of a nitrovasodilator selected from the group consisting of sodium nitroprusside, diazenium diolates, molsidomine, linsidomine chlorohydrate, S-nitrosothiols, organic nitrates, pharmacologically acceptable salts, esters, analogs, derivatives, prodrugs and inclusion complexes of any of the foregoing, and combinations thereof.

37. (New) A method of enhancing sexuality in a female having a clitoris comprising the step of topically administering to a surface of the clitoris a composition whose primary agent is a vasodilator and whose secondary agent is a carrier in which the vasodilator is dispersed to deliver it directly to said surface so that it is retained and absorbed thereby, said composition being in a formulation and in a dosage which is substantially free of toxicity and therefore does not give rise to an adverse reaction.